TESTIMONY SUBMITTED REGARDING CONNECTICUT RAISED BILL 5307

PUBLIC HEALTH COMMITTEE

Submitted by:

Andrew Friedell
Director, Government Affairs
Medco Health Solutions, Inc.

March 1, 2010

State Senator Jonathan Harris, State Representative Elizabeth Ritter and members of the Public Health Committee, my name is Andrew Friedell and I am a Director of Government Affairs for Medco Health Solutions, Inc., which is a pharmacy benefits management company, or "PBM." I would like to thank you for this opportunity to testify today regarding our concerns with Raised Bill 5307. We believe this legislation is not needed, that prescribers already have the authority to achieve the underlying intent through existing state law and that the issues raised by this bill can best be addressed by the doctor, patient and pharmacist -- not by the legislature. If enacted, this bill will result in added costs and make it harder for Connecticut patients to receive affordable prescription drug coverage.

Medco is a leading provider of comprehensive, high-quality, affordable prescription drug care in the United States. As a PBM, Medco is hired by large employers, unions, health plans and public sector entities to help manage the quality and affordability of the drug benefit these plans offer to their members or employees. Medco provides drug benefits to roughly 60 million people nationwide and over 18 percent of the Connecticut population. In 2009, we mailed approximately 990,000 prescriptions to state residents and we also operate a specialty pharmacy in Vernon, Connecticut.

We have serious concerns about Raised Bill 5307 because it seeks to carve one class of drugs -- anti-epileptic medications -- out of the state's generic substitution rules without any scientific evidence supporting such protections. This will drive up costs for patients and payors by making it harder for the patient to obtain a lower cost generic medication and by opening the door to additional legislation in the future seeking similar exemptions for other classes of medication.

The U.S. Food and Drug Administration, charged with approving new drug applications and applications for generic equivalent products, weighed in on similar legislation under consideration in the state of Iowa in a letter dated January 11 of 2008 (copy attached):

> *FDA is aware that certain individuals and groups have expressed particular concern about the switch of anti-epileptic drug products.* ***To date, we have no scientific evidence that demonstrates a particular problem with this group of products.*** *Further, there are frequently*

circumstances other than the switch that may cause untoward responses. We continue to follow-up such reports and interact with those concerned (emphasis added).

Furthermore, the FDA also noted that when a generic product is deemed to be therapeutically equivalent to the innovator product (as is the case with several drugs that would be subject to the provisions of this bill), there is no need for the prescriber to "approach any one therapeutic class of drug products differently from any other class…"[1]

In addition, the American Medical Association has also looked into this specific issue and determined in a letter dated August 30, 2007 that "After reviewing the scientific evidence, the CSAPH (Counsel on Science and Public Health of the AMA's House of Delegates, 2007) concluded that a separate, more stringent generic substitution process for NTI (narrow therapeutic index) drugs was unnecessary."[2]

In addition, I'd also like to draw the Committee's attention to an "Rx Watchdog Report" published earlier this year by AARP that focuses on this very issue. AARP highlighted the potentially large cost to public payors such as the state. I have attached a copy of this report to my testimony and ask that you consider their views on this matter as well.

Given that both the FDA and AMA have weighed in effectively opposing special rules for this class of medications and given that there is no scientific evidence indicating that such special treatment is warranted, we urge the committee to leave this as a matter best addressed in discussions between the doctor, patient and pharmacist. Clearly, it is critical that physicians educate their patients about these matters and that pharmacists always inform patients when changes are made to their drug therapy.

Prescribers already have the ability to indicate if and when a drug can be substituted and when it should not. They have the right to indicate "dispense as written" on the prescription; *they do not need additional legislation to underscore that authority*. This authority also applies to both brand and generic drugs. In other words, the state's "dispense as written" rule gives the physician the ability to designate that a patient receive either a specific brand medication ***or*** a generic version that is manufactured by a specific generic company. Therefore any risks associated with changes in therapy among these medications are easily addressable under current law. In limiting drug substitution, R.B.5307 creates new barriers between patients and safe and effective generic alternatives.

In addition, if the legislature decides to step in and limit generic substitution for this particular class of medications, it will no doubt open the door to addition legislation in the future seeking a similar exemption for other classes of medication. We fear that the passage of this legislation would be viewed by some as a "green light" to promote additional carve-out legislation that would further drive up the cost of prescription drug care.

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[1] Letter from Gary Buehler, R.Ph., Director of the FDA Office of Generic Drugs, to Ms. Nicole Schultz of the Iowa Pharmacy Association, dated January 11, 2008.

[2] Letter from Michael D. Maves, MD, MBA, Executive Vice President and CEO of the American Medical Association, to Mark Merritt, President and CEO of the Pharmaceutical Care Management Association, dated August 30, 2007.

Without any scientific evidence to justify these new rules, this legislation could result in significant and unnecessary increases in health care costs. In a time of rapidly escalating drug costs, we should be focused on encouraging the use of safe and effective cost control techniques, such as generic drugs, rather than discouraging them.

In summary, R.B. 5307 aims to mediate issues which should simply be addressed through the communications that the prescriber and pharmacist have with the patient. No additional legislation is needed at this time. Thank you for your consideration of our views. I would be happy to answer any questions that members of the Committee might have regarding my testimony.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

January 11, 2008

Ms. Nicole Schultz
Iowa Pharmacy Association
8515 Douglas Avenue, Suite 16
Des Moines, IA 50322

Dear Ms. Schultz:

This is in reply to your correspondence dated November 6, 2007, directed to Ms. Susan Winckler requesting that the FDA provide a statement regarding generic substitution, particularly with respect to anti-epilepsy drugs. It was forwarded to the Office of Generic Drugs for a reply.

The FDA has many years of experience in the review of generic drugs and assures the quality and equivalence of approved generic drug products. FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S., both brand-name and generic, meet specifications for identity, strength, quality, purity and potency. In approving a generic drug product, the FDA requires that the proposed generic product is demonstrated to be equivalent to the brand-name drug in both the rate and extent of absorption. As noted in the Preface to the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") (27th Edition),

> FDA classifies as therapeutically equivalent those products that meet the following criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the same active drug ingredient in the same dosage form and route of administration, and, (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent; (4) they are adequately labeled; (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations.
>
> FDA considers drug products to be therapeutically equivalent if they meet the criteria outlined above, even though they may differ in certain other characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time and other minor aspects of labeling (e.g., the presence of specific pharmacokinetic information) and storage conditions. When such differences are important in the care of a particular patient, it may be appropriate for the prescribing physician to require that a particular brand be dispensed as a medical necessity. With this limitation, however, FDA believes that products classified as therapeutically equivalent will produce the same clinical effect and safety profile as the prescribed product.

FDA is aware that certain individuals and groups have expressed particular concern about the switching of anti-epileptic drug products. To date, we have no scientific evidence that demonstrates a particular problem with this group of products. Further, there are frequently circumstances other than the switch that may cause untoward responses. We continue to follow-up such reports and interact with those concerned.

If FDA has determined a generic to be therapeutically equivalent to the innovator product, FDA continues to believe that:

- Additional clinical tests or examinations by the healthcare provider are not needed when a generic drug product is substituted for the brand-name product or vice-versa.
- Special precautions are not needed when a formulation or manufacturing change occurs for a drug product provided the change is approved according to applicable laws and regulations by the FDA.
- As noted in the "Orange Book," in the judgment of the FDA, products evaluated as therapeutically equivalent can be expected to have equivalent clinical effects whether the products are brand-name or generic.
- It is not necessary for the healthcare provider to approach any one therapeutic class of drug products differently from any other class when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration.

We continue to monitor, take seriously, and, if indicated, investigate reports of potential inequivalence of all generic drugs. The FDA is committed to approving high-quality generic drug products that can be used with confidence by the American public.

Sincerely,

Gary Buehler, R.Ph.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

cc: S. Winckler
C. Jung

AARP

February 2009

Rx Watchdog Report

Shining a light on the cost and quality of prescription drugs

Why Now? Some Want to Curb the Use of Generic Drugs

The U.S. economy has fallen into a recession, the costs of health care and prescription drugs are rising and many more individuals are expected to become uninsured over the coming year. By December of 2008, 44 states faced or are facing budget shortfalls. Yet in 2008 state legislatures saw the introduction of over 70 bills trying to limit the use of generic drugs that save state governments millions of dollars.

Current state generic substitution laws allow, or in some cases, require, pharmacists to dispense the generic equivalent of the brand name drug that has been prescribed if one is available. Generic drugs are approved by the Food and Drug Administration (FDA) as being as safe and effective as branded drugs, yet generic drugs cost on average 30 to 80 percent less than brand name drugs. The laws governing drug substitution vary by state, but all 50 states have passed legislation that allows pharmacists to make generic substitution and 15 states require it.

A prescriber always has the ability to prevent a generic substitution from occurring, often by writing "brand medically necessary" or "dispense as written" on the prescription.

But at the urging of the Epilepsy Foundation, the National Kidney Foundation, other patient disease groups and some pharmaceutical companies, state legislatures are faced with proposals that would limit the substitution of generics, often referred to as "carve-out" measures. Proposed carve-out measures would prevent pharmacists from

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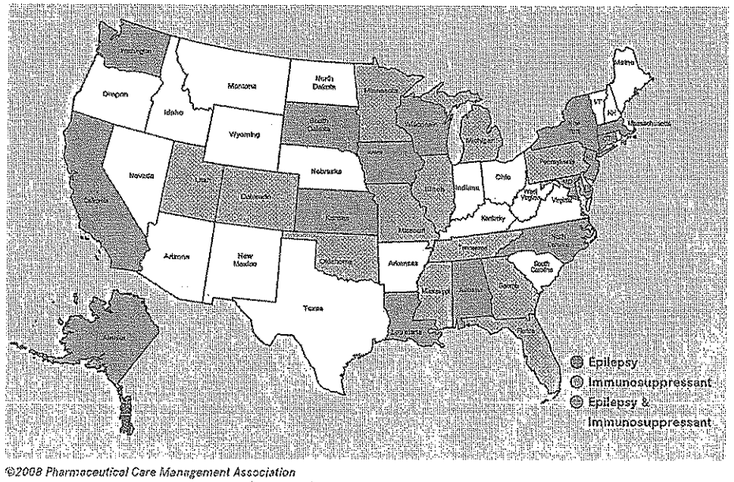
Generic Carve-out Legislation Introduced in 2008



Generics Drugs are Good Medicine

More than two thirds of prescriptions dispensed in the United States are filled with generic medicines. This level of generic utilization is at an all-time high of 67 percent—higher than many other countries in the world. So far, there has not been any scientific evidence that the increase in generic drug utilization in the U.S. has resulted in more adverse reactions or worse patient outcomes.

Yet there are still many misconceptions about generic drugs. "Generic drugs can be very useful for doctors and patients because they are bioequivalent to brand name drugs but available at a lower cost. However, there is a common misperception that brand name drugs are somehow superior to generic drugs. We sought to determine what the evidence was underlying this view," said Aaron S. Kessselheim, M.D., J.D., M.P.H., of the Division of Pharmacoepidemiology at Brigham and Women's Hospital. Kesselheim and colleagues recently published a meta-analysis in the *Journal of the American Medical Association* that found no evidence of the superiority of brand name drugs over generic drugs in the field of cardiovascular disease.

"This misperception is fueled in part by physicians and patients who don't understand the approval process required by the Food and Drug Administration (FDA)," Kesselheim said. "In addition, people may equate generic drugs with generic products they buy at the supermarket, like generic corn flakes or generic paper towels. Some people may equate such lower cost items with lower quality. But among drugs used for cardiovascular disease, we found no evidence that brand name products are more safe and effective than generic drugs," he added.

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Why Now? Some Want to Curb the Use of Generic Drugs continued

substituting a generic for its brand name counterpart in certain drug classes (like anticonvulsants) unless the pharmacist contacts the prescriber for consent, even when the prescriber has indicated clearly "dispense as written," or in simpler terms, "dispense as I ordered, which is generic unless otherwise specified" in most states.

AARP opposes these carve-out proposals because every state already has a version of a "dispense as written" law so ultimately the prescriber still has final authority and the patient may easily receive a brand name drug if the prescriber determines it is preferable. AARP also supports the wide use of FDA-approved generics as a mechanism to helping consumers gain access to affordable and safe treatment.

Supporters of carve-out measures argue that brand name drugs and their generic counterparts are not equivalent. The Epilepsy Foundation, for example, believes FDA guidelines that allow for a therapeutic range are too broad to ensure that each individual will receive the same amount of anti-epileptic drug when switching from a brand name to a generic anti-epileptic drug or from one generic to another. The FDA's position is supported by their own research and testing that finds no difference between brand name drugs and their generic counterparts (please see accompanying stories for more details).

Following The Money

There is a lot of money at stake, for all involved in this debate—consumers, pharmaceutical companies and the purchasers such as state governments. Officials with Massachusetts Medicaid program, for example, realized they were paying $10 million to $11 million a month for brand name drugs that had generic equivalents. After instituting a generic substitution policy, their spending subsequently dropped to between $200,000 and $300,000 a month. A similar policy, enacted in New York, is projected it will save the state $45 million dollars per year between 2009 and 2012.

In Florida in 2007, HB 849 was introduced, which is similar to many of the carve-out bills. It would have prohibited Florida licensed pharmacists from interchanging an anti-epileptic drug, brand or generic, to treat seizures or epilepsy without the prior notification and signed informed consent of the physician and patient. Florida's Agency for Health Care Administration estimated that the fiscal impact on current claim levels for the Medicaid-fee-for-service population would be $52 million dollars a year.

Key Brand Drugs Losing Patent Protection
More than $66 billion within next five years

2008	2009	2010	2011	2012
$12.8 Billion	$10.9 Billion	$7.8 Billion	$15.2 Billion	$19.6 Billion
• Altace • Cosopt, Trusopt • Depakote • Fosamax • Imitrex • Keppra • Lamictal • Risperdal • Wellbutrin XL 150 • Yasmin	• AdderallXR • AmbienCR • Cellcept • DepakoteER • Lovenox • Prevacid • Topamax • Valtrex	• Aricept • Arimidex • Cozaar/Hyzaar • EffexorXR • Flomax	• Actos • Caduet • Levaquin • Lipitor • Protonix • Zyprexa	• Avandia • Avapro, Avalide • DetrolLA • Diovan • Geodon • Lexapro • Plavix • Provigil • Seroquel • Singulair • Viagra

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> **"There is a lot of money at stake, for all involved in this debate–consumers, pharmaceutical companies and the purchasers such as state governments."**

Another example of a state that would have spent millions if a carve-out bill became law was Ohio. In 2008, a bill introduced would have increased the state's drug costs by more than $28 million a year, according to the Ohio Legislative Services Commission estimate. The bill sought to prohibit a pharmacist from interchanging drugs prescribed to treat epilepsy or seizures without the written consent of both the prescriber and patient (existing state law requires the pharmacy to inform the patient if a generic is available at a lower cost or equal cost and of his or her right to refuse the drug selected). In a letter to the Ohio Senate Committee, the Medicaid director described the administrative burden the legislation would impose on all involved as a "barrier to health."

Another important stakeholder, in addition to government and consumers, are the pharmacy benefit managers (PBMs) who administer prescription drug benefits for over 200 million people through health plans, unions, and employers. The Pharmaceutical Care Management Association (PCMA), a national organization that represents PBMs, released a study that estimated if generic carve-out legislation were enacted nationally in 2009 in the anti-epileptic, immunosuppressant and antipsychotic therapeutic classes, total drug costs to Medicaid, commercial payers and consumers would be $29 billion over the 2010 to 2019 period.

To date, carve-out legislation that requires a pharmacist to notify the prescriber or to obtain the consent of the prescriber and patient before dispensing a generic for the treatment of epilepsy and seizures has passed in Hawaii (2003), Tennessee (2007) and

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Utah (2008). For a more comprehensive list of state legislation, visit the National Conference of State Legislatures website at **www.ncsl.org/programs/health/rx-substitution08.htm.**

2009 promises to be another busy year for state lawmakers on this issue.

"Given the amount of bills dealing with this issue we saw last year, it is entirely likely such measures will be re-filed again," said Richard Cauchi, program director of the NCSL. "Legislators will continue to be concerned with patient access to prescription drugs but say they also must be sensitive to affordability and take action on both these issues," he added.

"Branded pharmaceutical companies, facing eroding pipelines for new, innovative drugs and the loss of patent protection on many of the popular, best-selling drugs in these 'carve-out' therapeutic classes, are aggressively protecting their market share while they can."

Why Now?

Branded pharmaceutical companies, facing eroding pipelines for new, innovative drugs and the loss of patent protection on many of the popular, best-selling drugs in these "carve-out" therapeutic classes, are aggressively protecting their market share while they can. More than three dozen commonly prescribed brand name drugs, representing annual U.S. sales totaling $67 billion, are facing generic competition between 2007 and 2012 (according to IMS Health, Global Pharmaceutical Sales by Region, 2007, 2008).

Three brand name epilepsy drugs—Depakote, Lamictal and Topamax—collectively earning more than $5 billion annually have or will lose their patents soon. Depakote has a generic as of 2008; Lamictal has a generic, as of 2008, for a six-month pediatric exclusivity, and Topamax had its patent extended until 2009. The appearance of a conflict of interest is difficult to ignore.

Many branded immunosuppressant and cardiovascular drugs will also soon face patent expiration and generic competition, with the result that patient groups such as the American Heart Association and the National Kidney Foundation, in addition to the Epilepsy Foundation, are becoming more actively involved in efforts to change drug substitution laws at the state level.

Several of the patient groups receive funding from the companies that make drugs for the medical conditions the groups represent.

But whether a conflict of interest between the branded pharmaceutical companies and the patient advocacy groups is real or perceived, many of these same groups and patients do frequently make the claim that patients experience adverse reactions as a result from their drugs being switched; whether it is from generic to brand, brand to generic, or generic to generic.

Given the critical issues involved in this debate AARP believes that the medical community, patients, consumers and lawmakers clearly need access to unbiased, objective and scientifically independent information about the prescription drugs they are prescribing, purchasing and receiving. And that the decision should remain between the prescriber and their patients.

For more information on the Epilepsy Foundation's position visit:

- **www.epilepsyfoundation.org/advocacy/care/genedrev.cfm**

Information from the American Heart Association and the National Kidney Foundation on this issue and their views can be found at:

- **www.americanheart.org/presenter.jhtml?identifier=3015266**
- **www.kidney.org/news/newsroom/newsitemArchive.cfm?id=138** ■

Legal Front News

Florida and 18 States Battle Prescription Drug Companies

Florida and 18 other states are involved in a class action lawsuit against Abbott Laboratories and French drug company Fournier Industrie et Sante and Laboratories Fournier, S.A. Florida Attorney General Bill McCollum alleges that the drug companies are blocking generic prescription competition through sham litigation designed to extend their patent and monopoly pricing power on the cholesterol drug TriCor. Abbott and Fournier are accused of deceiving the Patent and Trademark Office by repeatedly making minor changes in the chemical composition of TriCor to prevent equivalent generic substitutions, a kind of product switching that allows companies to extend the duration of the drug's patent and thus block generic versions from being made available to consumers.

"With rising fuel costs, falling housing values and investment markets in turmoil, Floridians 50+ are facing tough economic pressures," said Lori Parham, AARP's Florida state director. "Using generic medications is an important tool in holding down runaway costs in prescription drug costs. AARP applauds Attorney General McCollum's strong stand on behalf of older Floridians."

Florida and other states' public programs, such as Medicaid and state employees programs that are large purchasers of prescription drugs, would have to bear the cost of paying for brand name drugs if this lawsuit does not rule in their favor. ■

The FDA Approval Process

Portions of the following text was taken from a Dear Colleague letter written by the U.S. Food and Drug Administration. The full text of the letter, titled "Therapeutic Equivalence of Generic Drugs Letter to Health Practitioners," can be found at www.fda.gov/CDER/news/nightgenlett.htm.

Therapeutic Equivalence of Generic Drugs
Letter to Health Practitioners

For both brand name and generic drugs, FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S. meet specifications for identity, strength, quality, purity and potency. In approving a generic drug product, the FDA requires many rigorous tests and procedures to assure that the generic drug is interchangeable with the brand name drug under all approved indications and conditions of use. For these reasons, FDA-approved product labeling does not recommend that any additional tests need to be performed by the health care provider when a switch occurs from a brand name drug product to a generic equivalent drug product, from a generic equivalent to a brand name product drug, or from one generic product to another when both are deemed equivalent to a brand name drug product. Brand name drug products and therapeutically equivalent generic drug products are identified in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," frequently called the "Orange Book."

In addition to tests performed prior to market entry, the FDA regularly assesses the quality of products in the marketplace and thoroughly researches and evaluates reports of alleged drug product inequivalence. To date, there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand name drug. Questions have been raised in the past, as well, regarding brand name and generic products about which there could be concern that quality failures might represent a public safety hazard. FDA has performed post-marketing testing on many of these drugs to assess their quality. In one instance, more than 400 samples of 24 marketed brand name and generic drug products were tested and found to meet the established standards of purity and quality. Because patients may pay closer attention to their symptoms when the substitution of one drug product for another occurs, an increase in symptoms may be reported at that time, and anecdotal reports of decreased efficacy or increased toxicity may result. Upon investigation by the FDA, no problems attributed to substitution of one approved drug product for another have occurred.

"The FDA regularly assesses the quality of products in the marketplace and thoroughly researches and evaluates reports of alleged drug product inequivalence."

The FDA works with both brand name and generic drug product manufacturers after a drug product is in the marketplace to assure its quality. For example, brand name and generic drug product manufacturers may want to change the drug formulation, site of manufacture, or manufacturing process after the drug is in the marketplace. These types of changes can be put in place only after the drug manufacturer provides the FDA with sufficient evidence that the drug identity, strength, quality, purity and potency will not change.

There are products in which small changes in the dose and/or blood concentration could potentially result in clinically important changes in drug efficacy or safety. Usually, these drugs require frequent adjustments in the dose of the drug and careful patient monitoring irrespective of whether the drug is a brand or generic drug product. These drugs may sometimes be described in FDA-approved drug labeling as narrow therapeutic range drugs.

FDA may recommend to the manufacturers additional tests for approval of both brand name and generic products, depending on the complexity of a drug substance or drug product and also depending on whether small changes in the dose and/or blood concentration could result in changes in drug efficacy or safety. It may also require additional tests for certain post-approval changes in manufacturing. The agency's recommendation to the manufacturer for these additional tests is designed to give the practitioner and patient additional assurance of product quality and interchangeability. These additional requirements should not be construed to mean that additional clinical scrutiny is necessary when interchange occurs. If anything, the additional tests required of pharmaceutical manufacturers are designed to reduce, not increase, concerns on the part of patients and practitioners.

Based on the FDA's determination of therapeutic equivalence between generic and innovator drug products, the FDA concludes that:

- Additional clinical tests or examinations by the health care provider are not needed when a generic drug product is substituted for the brand name product.
- Special precautions are not needed when a formulation and/or a manufacturing change occurs for a drug product provided that the change is approved according to applicable laws and regulations by the FDA.
- As noted in the "Orange Book," in the judgment of the FDA, products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is brand name or generic drug product.
- It is not necessary for the health care provider to approach any one therapeutic class of drug products differently from any other class, when there has been a determination of therapeutic equivalence by the FDA for the drug products under consideration. ■

Looking Ahead: AARP State & Federal RX Advocacy Work in 2009

State

One of AARP's objectives is to make prescription drugs—a key component of health care—more affordable for all Americans.

AARP will be seeking:

- to maintain funding for State Pharmaceutical Assistance Programs (SPAPs), which provide subsidies to cover low-income individuals for prescription drugs. State government deficits threaten the funds that support these programs. AARP believes it is important for state policy makers to prioritize state funding for SPAPs and other critical programs that are vital to serving vulnerable persons.

- to oppose efforts that undermine generic drug substitution, so that consumers do not pay more than they need to for prescription drugs.

- to support and maintain the development of educational programs that provide unbiased information to physicians about prescribing options, in order to counteract the intensive marketing efforts by brand manufacturers.

Federal

AARP will be supporting and advocating for:

- the passage of the Access to Life-Saving Medicine Act that would grant the Food and Drug Administration (FDA) the authority to create a pathway for the approval of generic biological drugs. Biologic drugs hold the promise for treating many diseases such as cancer, multiple sclerosis and arthritis but can be very expensive drugs, costing consumers tens to hundreds of thousands of dollars each year. They now account for one out of eight prescriptions written, with sales over $75 billion in 2007. These high costs increase the risk that patients will forego treatment. In 1984, Congress approved the Hatch-Waxman Act, which created a pathway for FDA approval of generic forms of traditional prescription drugs. However, there is not yet any law authorizing the FDA to approve generic alternatives for biologic drugs. For more information on biologic drugs, see a past issue of *RX Watchdog* at **http://www.aarp.org/research/health/drugs/rx_watchdog.html**.

> "One of AARP's objectives is to make prescription drug–a key component of health care–more affordable for all Americans. "

- the passage of the Comparative Effectiveness Research Act of 2008, which would create an independent, nonprofit entity to conduct research on the comparative effectiveness of different treatments and publicize the results. One of the fundamental building blocks of a reformed health care system is the availability of scientifically valid, objective, comparative information about treatment options. Comparative effectiveness research—where pharmaceuticals, medical devices and medical procedures used to treat the same conditions are evaluated for their relative safety and effectiveness—has great potential to improve health care quality. Currently, many different entities both inside and outside the government engage in comparative effectiveness research. But inadequate agency funding, coupled with lack of standard methodologies makes it difficult to compare the research conducted. This legislation provides for a stable approach significant source of funding for the entity through an all-payer system.

AARP's full advocacy agenda can be found at **www.aarp.org/makeadifference/advocacy/articles/2009_legislative_priorities.html**. ■

Did You Know?

- Products generating $139 billion in branded sales in the top eight world markets will lose their patent protection by 2012.

- The U.S. generics market is currently valued at $33 billion compared with $34 billion last year, reflecting declining prices and fewer blockbusters losing patent protection in 2008.

- Some Part D Plans are charging additional costs to Medicare beneficiaries if they choose a brand name over a generic? Called "reference based pricing," the additional cost is typically the amount between the difference between the cost of the generic and brand name drugs, plus the co-payment, which in some instances can be the full cost of a brand name drug. AARP and other organizations wrote to the Centers for Medicare and Medicaid Services (CMS) and expressed their concern over the lack of transparency over the cost differences and issues warnings to beneficiaries.

- More than six in ten (62 percent) of AARP Medicare Part D survey participants said they always choose a generic over the brand name drug when a generic is available. Another quarter said they usually or sometimes do, and one in nine (11 percent) reported they never choose a generic over a brand. ■

Generics Drugs are Good Medicine continued

The FDA, which is responsible for testing and approving all prescription drugs on the market, has repeatedly assured the public that generic and brand name medicines have the same amount of active ingredient, strength, dosage, labeling, use and quality. Generic manufacturers are held to the same high quality manufacturing standards as brand name manufacturers licensed by the FDA to produce drugs (please see page 4 on the FDA approval process).

While Kesselheim and his co-authors were not surprised to find there was no evidence to support the notion that brand name drugs used in cardiovascular disease are superior to generic drugs, he was surprised to find a substantial number of editorials written by health care professionals in medical journals that counseled against the interchangeability of generic drugs. "We were taken aback by the disconnect between many of the editorials and the clinical trial evidence. Articles in medical journals generally have greater authority for physicians than those in the lay press, so they see this negativity and concern. These articles may help reinforce misperceptions among physicians about the safety and efficacy about generic drugs," he said.

"One reason for the heightened concern expressed in these editorials may be that the authors were communicating anecdotal experiences without evidence-based support. In addition, physicians are human beings and their opinions may be subconsciously influenced by advertising by brand-name manufacturers or conflicts of interest due to financial relationships with pharmaceutical companies," said Kesselheim.

Kesselheim wants physicians to step up to the plate and believes AARP can help, he said. "AARP can play an important role here by helping educate consumers. Our study indicated that consumers can feel confident asking their physicians about whether generic drugs might be appropriate for their cardiovascular disease and taking them if prescribed," he said.

"The FDA, which is responsible for testing and approving all prescription drugs on the market, has repeatedly assured the public that generic and brand name medicines have the same amount of active ingredient, strength, dosage, labeling, use and quality."

"Another important goal here is to get doctors to prescribe better," he said. "We as physicians need to follow evidence-based medicine, which often supports starting a patient on a generic drug. The fact is many people are on brand name drugs because they are swayed by advertising, when a generic drug may be appropriate for them. With more rational use of generic drugs, we can reduce patients' drug costs without detracting from high quality health care."

Several surveys have shown that older adults, who are disproportionately affected by chronic disease and likely to need medications taken regularly over long periods of time, resort to skipping doses, reducing doses, and forego their prescriptions altogether when faced with increased drug costs. This can lead to adverse health outcomes and more expensive care and treatment later on. In contrast, researchers have found that patients who begin treatment by taking lower-cost generic medications are more likely to take their medicines as prescribed.

Look for more upcoming articles on the wise use of generics in *Rx Watchdog*.

Kesselheim's report, "Clinical Equivalence of Generic and Brand name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-Analysis," can be found in the December 3, 2008 *Journal of the American Medical Association* at **www.jama.ama-assn.org/cgi/content/short/300/21/2514**.

AARP's report, "Strategies to Increase Generic Drug Utilization and Associated Savings," can be found at **www.aarp.org/research/health/drugs/i16_generics.html**. ■

AARP

Rx Watchdog Report

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www.aarp.org/issues/rx_watchdog